

Exhibit 15B

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Another item the opponent Granini fails to point out is that calcium supplementation of juices is not one of the objects of this reference. Indeed, nothing is stated at all about calcium supplementation of beverages. Instead, calcium is added together with other cations for purposes unrelated to calcium supplementation, i.e. improving the flavour and body impression of the beverages. The only object of this document that coincides with that of the patent attacked is solubilization of the calcium. Moreover, Document (2) does not inherently disclose high level (e.g. 0.10 % or higher) calcium addition beverages, and in particular fruit juice containing beverages. Embodiments 1-9 of this reference all involve **low level calcium addition** (i.e. from 0.014 to 0.046 %). As previously pointed out, all of these embodiments involve **carbonated beverages containing no juice**. Given the wide ranges taught for the total cation level, i.e. at least 0.03 %, preferably 0.1 to 0.6 % for carbonated beverages, this Document would not direct one skilled in the art towards the claimed single-strength juice products, particularly those containing higher level of solubilized calcium.

The opponent Granini GmbH furtheron alleges that Document (1) teaches a minimum calcium content of "at least 0.03 %". This statement, however, mischaracterized what "at least 0.03 %" refers to, i.e. it refers to the **total level of cations** (page 6, lines 25-27) not just the calcium component. Moreover, Granini's reliance on the preferred range of the total cations (i.e. 0.1-0.6%) is misplaced, since, as pointed out above, Document (1) says this range is preferred liquid **carbonated beverages**. Granini has provided no reasonable basis for extrapolating from the total cation level disclosures that are primarily directed towards carbonated beverages containing no juice, to the claimed single-strength products containing high levels of juice (at least 45%) and preferably high levels of solubilized calcium (at least 0.10 %).

Therefore, this document cannot make obvious the subject matter claimed. This specifically in view of the fact that when taking into consideration the disclosure of Document (1), the man of the art clearly would not have reduced the cation component to calcium but would have expected that this would result in a product having unsatisfying organoleptic properties, so that it clearly was not obvious to try the elimination of potassium and/or magnesium and phosphoric acid from the compositions disclosed in the reference and to see as to what the properties such a product may have, specifically when taking into consideration that at the same time it would become necessary to increase the amount of calcium over that defined in this document, specifically embodiment 4 covering a single-strength beverage comprising only 0.046% by weight of calcium.

7.2. GB-A-1 440 161 (2) (Nishiyama)

This reference is directed to a **milk drink** containing fruit juice and solving the problem that milk normally coagulates when adding fruit juice. Since the subject matter claimed in the patent attacked clearly excludes such milk drinks, the man of the art

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will not be lead to the subject matter claimed when taking into consideration the information provided by this document. Specifically also in view of the fact that sodium carboxymethylcellulose is a necessary component used in a considerable amount in the fruit juice composition to be added to the milk, a component not necessary according to the invention.

7.3. US-A-3 114 641 (3) (Sperti)

The problem underlying this prior art document is the provision of a citrus juice product which can be extended by dilution and provides an extended juice, which retains the full and natural flavors characteristic of the natural, whole juice.

This problem is solved by an orange juice product comprising sugar and citric acid in a specific amount, a buffering agent sufficient to maintain the pH of the extended products substantially in the range of 3.4 to 3.6 and a small quantity of a trace mixture consisting of in admixture sodium succinate, tartaric acid and potassium acetate (claim 1). Since the trace mixture necessary according to this prior art comprises components, which are not used in the present invention, the subject matter of the European Patent attacked cannot be made obvious by this document. Even when claims 3 and 4 make reference to the use of calcium chloride and malic acid as possible additives, this cannot be considered to direct the man of the art to the present invention, because calcium chloride cannot be used according to the present invention in that on the one hand it can impart undesirable brackishness to the juice as stated in page 2, lines 39 and 40 of the patent and because of the fact that it will add chloride ions, the content of which is in accordance with feature e of claim 1 restricted to amounts below 0.07 % by weight.

Therefore, this Document (3) as well leads the man of the art into quite another direction.

7.4. US-A-3 657 424 (4) (Aktins)

The problem of this prior art document is to provide citrus juices with increased amounts, beyond what is naturally present, of certain ions naturally present in the unaltered citrus juice in order that the loss of these ions from the bodies of individuals may be supplemented (column 2, lines 34 to 38).

This problem is solved by adding sodium chloride and optionally potassium chloride and calcium chloride to the citrus juice. The Examples demonstrate that the fruit juices always comprise the chlorides of sodium, potassium and calcium.

From claim 1 and the disclosure in the last paragraph of claim 2 of this document it

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can furtheron be taken that the "maximum permissible amount" of the calcium salt is about **0.04 weight %** which is below the lower limit used according to the present invention. Even when it is stated that the calcium salt may be a citrate as well, there is no reference in this document to the solubilization of the calcium nor to the acid component comprising citric acid and malic acid in the amounts defined, and of course no reference as to the premix-method used in the process of the European Patent 0 244 903.

Therefore, this document as well cannot lead the man of the art to the subject matter claimed.

7.5. JP-A-54-8767 (5) (Kaji)

This document relates to a calcium enriched soft drink containing calcium salts of edible organic acids such as calcium citrate, calcium malate, calcium lactate, calcium tartrate etc. (c.f. the claim of this document). However, this prior art document calls for the addition of **pre-manufactured salts of calcium**, such as the salts referred to above. Therefore, this reference only documents the prior art already discussed to in the introductory part of the description, which covers the addition of calcium salts to fruit juice, which is to be considered as not useful for providing the object of the present invention, specifically when taking into consideration that the calcium citrate referred to in this document will be in a thermodynamically stable form and therefore rather insoluble in the fruit juice.

Furtheron, the soft drinks disclosed in this reference appear to contain minimal juice, i.e. about 4% by weight based on the one example given. Accordingly, this reference cannot provide any hint to teach calcium supplemented single-strength beverages containing significant amounts of juice, i.e. at least 45% fruit juice.

Moreover, this document teaches calcium fortification at too high a level for single-strength products. The soft drinks referred to in this document contain on a calculated basis 0.6 % calcium, versus the maximum of 0.26 % for the claimed single-strength products of the patent under attack. Calcium, at the level taught by Document (5) will precipitate out of the products described, a fact, which can be proved by the patent owner if considered necessary by the Opposition Division.

Therefore, this document as well cannot be detrimental to the inventive step of the subject matter claimed.

7.6. JP-A-56-97248 (6) (Kawai)

This reference involves the preparation of calcium citrate/malate by dissolving: (1)

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less than 70% citric acid and greater than 30% malic acid in water and then neutralizing this acid solution with calcium hydroxide and calcium carbonate; or (2) sodium citrate and sodium malate in water and then adding calcium chloride to this solution to form a crystalline precipitate. The calcium citrate/malate obtained is stated to be useful as a calcium supplement in food and drinks for which clarity is important (page 5, lines 10-12). It is stated further on in this document that the combination of calcium citrate/malate increases the solubility of calcium citrate by three times or more at a pH of 6-6.5, making it possible to use calcium citrate in food preparations, especially transparent drinks.

Although disclosed in this reference as being more soluble, the specific water solubility tests performed suggest a lack of complete solubility for calcium citrate/malate. Reference may be made to the last paragraph of the German translation of this document submitted by the opponent Niederrhein-Gold. Moreover, this document nowhere teaches combining this calcium citrate/malate with fruit juice. Indeed the reference to its use in transparent drinks does not suggest juice-containing beverages. In the absence of a specific teaching of use in juice, it is unlikely one skilled in the art would add calcium citrate/malate to juice based on the disclosure in this reference, especially given the lack of complete solubility in water.

Therefore, this document discloses only that the combination of calcium citrate with calcium malate provides a combination which allows for the dissolution of a higher amount of calcium and that such composition can be used in food products, specifically in drinks which must be transparent.

However, this information will not lead the man of the art to the subject matter of the present invention, in that no help is provided as to have to solve the problem referred to above. For doing this, the man of the art needs more than the information that a combination of calcium citrate and calcium malate in a specific ratio may have a higher solubility than calcium citrate alone, and that it is necessary to know that a specific amount of solubilized calcium must be added to the fruit juice beverage in combination with a specific combination of acid components, which in fact are not to be considered a mixture of calcium citrate and calcium malate, a specific amount of fruit juice, a specific sugar content, an upper limit of the chloride ion content and the fact that the beverage is substantially free of added protein. Since with respect to these combination of specific features Document (6) does not provide any relevant information at all, this document as well cannot make obvious the subject matter claimed.

7.7. Chemical Abstracts, Vol. 90 (1979), 90:185216z (7) (= (5))

This document corresponds to reference (5) and therefore has already been considered above.

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7.8. EP-A-0 22 7 174 (8) (Nakel)

This document is relevant only as far as novelty is concerned and not to be considered in deciding whether there has been an inventive step or not.

7.9. US-PS 2 325 360 (9) (Ayers)

Briefly, this Document involves a method for replacing gases removed during deaeration of fruit juices, such as orange juice, with carbon dioxide.

It is stated in the introductory part of this Document (9) that according to conventional methods the extracted juices are first deaerated to remove the oxygen, which assists in preventing oxidation and flavor charges, whereafter the product is pasteurized and packaged. Since the deaeration gives the product a flat taste, the method disclosed comprises the introduction of a step after the pasteurizing step which comprises the replacement of the gases removed in the deaeration step with carbon dioxide. This is done by dropping dry calcium carbonate or a mixture of dry carbonate and citric acid into the can in which the hot pasteurized juice is contained, thereafter the can is immediately sealed and the reaction between the calcium carbonate and the normal acid of the juices and, if desired, added citric acid, releases the required amount of carbon dioxide in the sealed can (column 1, lines 16 to 45).

While it is disclosed in this Document that one advantage of the method described is the increasing of the calcium content of the juices, unlike European Patent 0 244 903, the primary objective of this reference is to generate carbon dioxide in the head space of the juice product to improve its flavour and to **avoid denting of the container** due to the vacuum that is created during "hot packing" of the juice (page 1, righthand column, line 53 to page 2, left-hand column, line 2). It is stated in this reference that calcium carbonate is particularly suitable for their method due to its delayed action and for "increasing the calcium content of the juice". However, increasing calcium content of the juice is clearly a secondary objective. Indeed, it is stated that sodium carbonate can be substituted for calcium carbonate (page 1, righthand column, lines 28 and 29).

Basically, this Document (9) provides the man of the art with the information that the necessary carbonization of fruit juice can be obtained by reacting calcium carbonate with citric acid in a closed container in the presence of the fruit juice. This will by no means be considered by the man of the art to provide a guidance leading him to the subject matter claimed. Even when it is stated that in place of the preferred citric acid also other organic acids, such as tartaric and malic acid may be used, this will not lead the man of the art to the specific acid component used according to the invention, let alone its combination with the other features of claim 1. Even when by chance when using malic acid in a citrus fruit juice citric acid and malic acid will be

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present at the same time, this will not call for the specific feature of the present invention to add a precisely defined amount of a precisely defined acid component juicy fruit juice and the solubilized calcium.

Therefore, this document as well will not direct the man of the art to the subject matter claimed. This becomes clear furtheron when taking into consideration that this document has already been published in 1943 without having had any effect as to solving the problem as it is now solved by the present invention.

7.10. RSK-Werte, Verlag Flüssiges Obst GmbH /1987), 43-51 (10)

This document has only been cited by the opponent Peter Eckes KGmbH for demonstrating that orange juice comprises a sugar content of 11.18 to 13.44° Brix. Otherwise this document is irrelevant, specifically in view of the fact that it is not published before the priority date of the European Patent.

7.11. GB-A-2 095 530 (11) (De Rham)

This document as well will lead the man of the art into quite another direction, in that it covers a process for the production of an **acid beverage enriched in protein**, particularly a fruit juice beverage or a fruit flavored beverage comprising lactic proteins, notably caseinates, in which beverage the proteins remain completely dissolved.

According to this process 5 to 50 mM calcium are added in the form of the chloride, acetate, tartrate, malate or lactate, and the pH may be adjusted using any strong edible acid, such as hydrochloric acid or an organic acid, such as acetic acid, tartaric acid, malic acid or lactic acid.

While it is stated in page 1, lines 37 to 40 that the double advantage of this technical teaching should be seen in the fact that it allows the production of acid beverages enriched in vegetable proteins, in which these proteins are and remain soluble, and that the acid beverage which is obtained is also enriched in calcium in a proportion which may obtain that which is normally found in cows milk, this cannot provide the man of the art with the specific combination of features of the present invention with which a completely different problem is solved.

Therefore, even though this document makes reference to the positive effect of enriching beverages in calcium, it leads the man of the art into quite another direction, i.e. to the production of beverages enriched in protein, which is not that what the present invention wants to obtain.

Therefore, also with respect to this document the subject matter claimed comprises

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the necessary inventive step.

7.12. Combination of the References

Since the references cited are directed to solving a large number of different problems in different ways, even a combination of the disclosure of the references will not lead the man of the art not having knowledge of the subject matter claimed to the present invention, i.e. a specific combination of features, with which a specific problem is being solved in a very elegant and successful way as demonstrated by the market success of the product claimed.

8. The Subclaims

In view of the fact that the dependent subclaims comprise preferred embodiments of the independent claims 1, 5 and 14, they are novel and based upon an inventive step as well, even though some of the features of these subclaims as such they already have been disclosed in one of the references cited. Since these subclaims also comprise the subject matter of their respective main claims, it is not possible, as the opponent Niederrhein-Gold Tersteegen GmbH & Co. KG has done, to exclusively look at the features of the subclaims and consider them to be either not novel or not based upon an inventive step without seeing their disclosure in the context with the preceding claims to which they make reference.

8.1. The Claimed Concentrate Products

The basic position of the opponents is that it is a trivial exercise to go from calcium supplemented single-strength juice products, to calcium supplemented juice concentrate products like those of claim 5-7 of European Patent 0 244 903. For example, the opponent Peter Eckes KGmbH essentially characterizes the claimed concentrate products as merely increasing the components of the claimed single-strength products by a factor of 3-5. This "trivial to do" theme is accorded in the statements of the other opponents.

Reality says that going from single-strength to concentrate products requires more than just increasing the level of components by a factor of 3-5. The patent owner's **practical experience** has been that formulation of calcium supplemented juice concentrate products is not as trivial as the opponents make it out to be. Calcium solubilization, particularly at high calcium levels, is extremely difficult in juice concentrate products. Relative to single-strength products, there is simply less available water to solubilize the calcium. This lack of available water is one reasons why the claimed premix method was developed so that concentrate products could be formulated.

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Solubilization of calcium in juice concentrate products becomes a particularly trying problem as to the level of juice increases, i.e. to 95% or higher. Higher juice levels mean a greater concentration of solids in the products, i.e. even less water available for the solubilization of calcium.

While the opponents merely argue that the subject matter of the claims directed to the concentrated products only comprises 3-5 fold extrapolation of single-strength products, this is not in consistency with the prior art cited. Much of the art, in particular that cited by the opponents, on adding calcium to juice is directed towards single-strength products. For example, Document (9) involves only calcium addition to single-strength orange juice. Document (6) is not directed at all at formulating juice products, much less juice concentrate products. Document (1) describes the formulation of beverage concentrates, however, as previously pointed out, is essentially directed at carbonated beverages that do not contain juice, and would therefore not be particular relevant to the claimed juice concentrate products.

8.2. Claimed Premix Method

Like the claims directed to the juice concentrate products, the opponents essentially treat the claimed premix method as trivial. For example, opponent Peter Eckes KGmbH characterizes the claimed premix method as merely diluting the premix solution of solubilized calcium and acids with juice and water. In actuality, it is usually the other way round, i.e. the juice is diluted with the premix solution. The positions of the other opponents are similar in that they rely primarily on the art that teaches, at most, formation of the premix solution only.

The claimed premix method is not nearly as trivial as the opponents make it out to be. At the priority date of the patent attacked, this premix method was the only practical way the patentee was aware of for formulating calcium supplemented juice products, particularly concentrate products containing high levels of calcium, e.g. levels of 0.10 % or higher. For example, direct addition of calcium carbonate with or without citric acid as taught by Document (9) causes a number of significant problems that are alluded to at page 8 of the patent under attack. These problems include undesirable foaming and loss of volatile flavour compounds, inadequate solubilization of the calcium, especially when concentrated juices used, in the presence of residual carbonation that can impart unpleasant spoiled fermented notes, especially in orange juice products. Moreover, the process disclosed in Document (9) facilitates solubilization of calcium because the juices are "hot" at the time of calcium carbonate addition. Such "hot" processing is not suitable for chilled single-strength, and especially frozen concentrate products.

The direct addition of calcium carbonate to fruit juice has real disadvantages, such a

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considerable foaming of the reaction mixture due to carbon dioxide evolution, which would make pumping and further processing of the concentrate extremely difficult. Another advantage of the premix method claimed is that it permits the use of other sources of calcium, particularly calcium hydroxide, which cannot be used by direct addition to the fruit juice, because this material is difficult to dissolve and, more significantly, the color of the juice significantly darkens and becomes green in color after calcium addition, an effect, that does not happen in the method claimed.

A key aspect of the claimed premix method that is not taught in the references cited by the opponents is the stability of the soluble calcium species in the initial premix solution. As taught at page 6, lines 43-50, of European Patent 0 244 903, the initial premix step forms an at least meta-stable solution of solubilized calcium containing the more highly soluble calcium citrate and malate species. As also pointed out, without added stabilizers, such as sugars or concentrated juice, these highly soluble calcium citrate species are stable in the premix solution for periods up to only about a few hours. After this short period of time, the highly soluble citrate species tend to disproportionate to the corresponding acid and the more thermodynamically stable, **insoluble** calcium citrate salts.

That this premix solution of highly soluble calcium citrate and malate species is thermodynamically unstable is apparently shown in Document (6) and in particular in Practical Example 1. In Practical Example 1, citric and malic acid (mole ratio 1:1) were dissolved in water, heated to 50 to 60°C and then calcium carbonate was added. A white crystalline mud formed gradually and filled the container, which, after standing for three hours, was separated from the mother liquid. In other words, Practical Example 1 of Document (1) probably obtained the more thermodynamically stable, insoluble calcium citrate salts. If anything Practical Example 1 of this document would clearly teach away from the claimed premix method. This is particularly true since Document (6) nowhere suggests combining the calcium citrate/malate obtained with fruit juice.

In arguing that the claimed premix method lacks novelty, opponent Deutsche Granini relies on Document (1) and in particular embodiments 1, 5 and 9 to show formation of the premix solution of solubilized calcium and acids. However, the opponent therefore makes a quantum leap in logic in saying that this document suggests mixing this "premix solution" with a juice concentrate. There is a key item missing in Granini's logic: Document (1) nowhere teaches combining this "premix solution" with juice concentrate. As previously pointed out, embodiments 1, 5 and 9 of Document (1) involve **carbonated** beverages which contain **no juice**. Accordingly, Document (1) and in particular embodiments 1, 5 and 9 do not disclose or suggest the claimed premix method.

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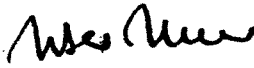
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9. Conclusion

As has been pointed out above, the subject matter of the claims herewith submitted are not disclosed in the references cited and comprise the necessary novelty. Since the references cited as well do either considered as such or in combination cannot lead the man of the art to the subject matter claimed but to a large extent lead him to another direction, the subject matter claimed is also based upon an inventive step.

Therefore, the above requests are justified and fully substantiated.

Respectfully submitted for the patent owner,


Dr. N. ter Meer
Patentanwalt/European Patent Attorney
- Association No. 6 -

Encls.:

New claims 1 to 19, 8-fold
6 Copies for the other parties

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The Procter & Gamble Company EP 0 244 903

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New Claims

1. A calcium-supplemented single-strength fruit juice beverage comprising a cation component and an acid component **characterized in that** it is substantially free of added protein and comprises:
 - a. from 0.05 to 0.26 % by weight solubilized calcium as the cation component
 - b. from 0.4 to 4 % by weight of a mixture of citric acid and malic acid in a weight ratio of citric acid:malic acid of from about 5:95 to 90:10 as the acid component;
 - c. at least 45% fruit juice;
 - d. a sugar content from 2 to 16° Brix; and
 - e. no more than 0.07 % by weight chloride ion,with the exclusion of beverages comprising 0.3 vol. or more of CO₂.
2. The beverage of Claim 1, **characterized in that** it further comprises aspartame and further characterized in that said sugar content is from 2 to 8° Brix.
3. The beverage of any of Claims 1 to 2, **characterized in that** said solubilized calcium comprises from 0.10 to 0.15% by weight of the beverage and further characterized in that said acid component comprises from 0.8 to 1.8% by weight of the beverage.
4. The beverage of any of Claims 1 to 3, **characterized in that** it comprises no more than 0.03% by weight chloride ion.
5. A calcium-supplemented fruit juice concentrate **characterized in that** it is substantially free of added protein and comprises:
 - a. from 0.15 to 1.30 % by weight solubilized calcium as the cation component
 - b. from 1.2 to 20 % by weight of a mixture of citric acid and malic acid in a weight ratio of citric acid:malic acid of from about 5:95 to 90:10 as the acid component;
 - c. concentrated fruit juice; and
 - d. a sugar content from 6 to 75° Brix, the content of the concentrated fruit juice being such that reconstitution with water yields a fruit beverage comprising at least 45% fruit juice.
6. The concentrate of Claim 5, **characterized in that** it has been frozen.
7. The concentrate of any of Claims 5 to 6, **characterized in that** said solubilized calcium comprises from 0.3 to 0.75% by weight of the concentrate and further characterized in that said acid component comprises from 2.4 to 9% by weight of the concentrate.

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- 1 8. The beverage or concentrate of any of Claims 1 to 7, characterized in
that said fruit juice is citrus juice.
9. The beverage or concentrate according to Claim 8, characterized in
that said citrus juice is orange juice and further characterized in that said
5 weight ratio of citric acid:malic acid is from 60:40 to 90:10.
10. The beverage or concentrate according to Claim 9, characterized in
that said orange juice comprises from 50 to 70% of the beverage of concen-
trate.
- 10 11. The beverage or concentrate according to Claim 10, characterized in
that said orange juice comprises at least 95% of the beverage or concen-
trate.
12. The beverage or concentrate according to Claim 8, characterized in
15 that said citrus juice is grapefruit juice.
13. The beverage or concentrate of any of Claims 1 to 7, characterized in
that said fruit juice is apple juice and further characterized in that said
weight ratio of citric acid:malic acid is from 30:70 to 50:50.
- 20 14. A method for preparing a calcium-supplemented fruit juice product
according to anyone of claims 1 to 13, characterized in that it comprises
the steps of:
- a. forming an at least meta-stable aqueous premix solution of solubi-
lized calcium from water, an acid component comprising from 0 to 90% by
weight citric acid and from 10 to 100% by weight malic acid, and calcium
25 source selected from the group consisting of calcium carbonate, calcium
oxide, and calcium hydroxide; and
- b. combining the premix solution of solubilized calcium with fruit
juice material comprising concentrated fruit juice having a sugar content
of from 20 to 80°Brix, to provide a calcium-supplemented fruit juice pro-
duct having: (1) at least 0.05% solubilized calcium; (2) at least 45% fruit
30 juice; and (3) a sugar content of from 2 to 75°Brix.
15. The method of Claim 14, characterized in that the premix solution of
solubilized calcium is formed by the step of: (1) forming an aqueous solu-
tion containing the acid component; and (2) adding the calcium source to
35 the acid component-containing aqueous solution.
16. The method of any of Claims 14 to 15, characterized in that the fruit
juice is concentrated orange juice and further characterized in that the
acid component comprises from 15 to 60% by weight citric acid and from
40 40 to 85% by weight malic acid.

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1 17. The method of any of Claims 14 to 16, **characterized in that the calcium source is calcium carbonate and further characterized in that the weight ratio of total acids to calcium in the premix solution is from 1 to 6.**

5 18. The method of any of Claims 14 to 17, **characterized in that the premix solution of solubilized calcium further comprises concentrated orange juice in an amount sufficient to provide a sugar content in the premix solution of from 2 to 12° Brix.**

10 19. The method of any of Claims 14 to 17, **characterized in that the premix solution of solubilized calcium further comprises sugar in an amount of from 2 to 40° Brix.**

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